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Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

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Serial No.: 10/728,577

Confirmation No.: 8901

Filed: 5 December 2003

For: POLYMER COMPOSITIONS WITH BIOACTIVE AGENT, MEDICAL ARTICLES, AND METHODS**Remarks**

The Office Action mailed 30 November 2007 has been received and reviewed. Claims 2-26, 60, 71, and 74-76 having been amended, and claims 1, 27-59, 61-70, and 72-73 having been cancelled, without prejudice, the pending claims are claims 2-26, 60, 71, and 74-76. Reconsideration and withdrawal of the rejections are respectfully requested.

Claim 71 has been written in independent form, incorporating the language of claim 1, from which it previously depended. Claim 74 has been rewritten in an analogous manner to that of claim 71. All claims are now directed to wound dressings.

Information Disclosure Statement

A Supplemental Information Disclosure Statement was submitted by Applicants on May 11, 2007. However, Applicants received an incomplete initialed copy of the 1449 forms submitted with the Supplemental Information Disclosure Statement indicating that the listed documents were considered by the Examiner. For the Examiner's convenience, a copy of page 3 of the 1449 form is attached as EXHIBIT A. Consideration of each of the documents listed on the attached 1449 form(s) is respectfully requested. Pursuant to the provisions of M.P.E.P. §609, Applicants further request that a copy of the 1449 form(s), marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

Obviousness-Type Double Patenting Rejections

Claims 1-26, 54, 55, 60, 71, and 74-76 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 12-51, 53-55, 58-93; 1-34; and 1-44 of copending Application Nos. 10/728,439; 10/387,236; and 10/728,446.

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Claims 1-26, 54, 55, 60, 71, and 74-76 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/729,114 in view of Asmus (U.S. Patent No. 5,270,358).

Upon an indication of otherwise allowable subject matter and in the event these rejections are maintained, Applicants will provide an appropriate response.

The 35 U.S.C. §112, First Paragraph, Rejection

The Examiner rejected claims 1-26, 54, 55, 60, 71, and 74-76 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner alleged that amended claim 1 and new claim 74 recite solubility of the silver compound without designating the solvent. The Examiner's attention is directed to the fact that each of these claims recites "the silver compound has a solubility in water of at least 0.1 gram per liter." Applicants are unclear as to the problem with the arrangement of this language. Applicants believe that the previous amendment to claim 1 (which recited "in water" twice) to remove one of the two "in water" clauses may have caused this rejection. If not, however, clarification is requested.

The 35 U.S.C. §103 Rejection

The Examiner rejected claims 1-17, 20-23, 54, 55, and 74-76 under 35 U.S.C. §103(a) as being unpatentable over Lorenzi et al. (U.S. Patent No. 6,217,889). This rejection is respectfully traversed. It is noted that claim 71 was not included in this rejection. Accordingly, claim 71 has been rewritten in independent form. Claim 74 has been amended in an analogous manner. Thus, although Applicants do not agree with this rejection, these amendments have been made (rendering this rejection moot) solely in the interest of expediting prosecution.

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For: POLYMER COMPOSITIONS WITH BIOACTIVE AGENT, MEDICAL ARTICLES, AND METHODS**The 35 U.S.C. §102/103 Rejection**

The Examiner rejected claims 1-26, 54, 55, 60, 71, and new claim 75 under 35 U.S.C. §102(b) as being anticipated by, or in the alternative, under 35 U.S.C. §103(a) as obvious over Asmus (U.S. Patent No. 5,270,358). This rejection is respectfully traversed.

Applicants reiterate the previous arguments regarding Asmus. Specifically, Asmus discloses "silver oxide, and silver and its salts" generically as examples of a "wide variety of [antimicrobial] agents" (see, e.g., column 12, lines 27-28). There is no disclosure of copper compounds or zinc compounds in the list of antimicrobial agents in column 12, lines 27-44, of Asmus. Applicants' claims recite that the bioactive agent is selected from the group consisting of a silver compound, a copper compound, a zinc compound, and combinations thereof, wherein the silver compound has a solubility in water of at least 0.1 gram per liter.

Not all silver compounds have a solubility in water of at least 0.1 gram per liter as pointed out in Applicants' previous Amendment (see, the CRC Handbook of Chemistry and Physics, 64th Edition, page B-137, previously submitted). The Examiner stated in the Office Action at page 7 "Regarding a)": "It is brought to applicant's attention that the claim generically claims a silver compound and applicant's own admission appears to question applicant's claim to all silver compounds having the claimed solubility." It is not clear what this means. Applicants are not claiming all silver compounds; rather, the claims recite a specific group of silver compounds, i.e., those silver compounds that have a solubility in water of at least 0.1 gram per liter. Although this is not a list of individual compounds, it nevertheless is a defined group of compounds that can be easily identified. It does not encompass all silver compounds. Furthermore, there is no teaching or suggestion in Asmus to select silver compounds having this recited solubility in water.

Asmus discloses a genus of silver compounds, in addition to numerous other antimicrobial agents, and Applicants' claims recite a species of silver compounds (i.e., those having a solubility in water of at least 0.1 gram per liter). The Examiner stated in the Office Action at page 7 "regarding b)": "silver oxide is soluble in other solvents . . . the amendment of

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the claim 1 deleting the solubility in water may support the solubility of silver oxide in other solvents.” Applicants did not previously amend claim 1 to delete the solubility in water; rather, claim 1 was amended to recite duplicate language. Each claim currently recites a silver compound having solubility in water of at least 0.1 gram per liter. Again, there is no teaching or suggestion in Asmus to select silver compounds having this recited solubility in water.

The Examiner stated in the Office Action at page 7 “regarding c)”: “Silver compound in Asmus . . . is silver oxide or silver salts.” Applicants repeat the previous arguments that there is no teaching or suggestion to one of skill in the art that would guide them to select a silver compound having a solubility in water of at least 0.1 gram per liter from the wide variety of antimicrobial agents disclosed by Asmus. There is no teaching or suggestion to one of skill in the art that would guide them to select such bioactive agents and combine them with the other components in a manner to produce a polymer mixture (comprising the organic polymer matrix and the microparticles comprising an amine-containing organic polymer), wherein at least a portion of the bioactive agent is incorporated within the microparticles. Also, there is no teaching or suggestion that the techniques used to make the composition of Asmus would result necessarily in incorporating at least a portion of the bioactive agent, regardless of what it is, within microparticles.

Furthermore, there is no teaching or suggestion in Asmus of a nonadherent composition. Asmus is directed to a gel-adhesive composite, i.e., a dispersed gel in an adhesive matrix. In contrast, Applicants claims are directed to a wound dressing that includes a nonadherent polymer composition. As explained at page 4, lines 3-10 of Applicants’ specification, the polymer composition itself is nonadherent (to steel per the test outlined, and preferably to wound tissue), although the nonadherent composition could be used in combination with a pressure sensitive adhesive, for example, in an article (e.g., a wound dressing). There is no teaching or suggestion in Asmus (or any motivation provided by any of the other documents cited by the Examiner) to make a nonadherent composition.

Applicants respectfully request reconsideration and withdrawal of the rejection under 35

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U.S.C. §102(b), or in the alternative, under 35 U.S.C. §103(a).

Summary

It is respectfully submitted that the pending claims 2-26, 60, 71, and 74-76 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

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Feb. 21, 2008

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 21st day of February, 2008, at 3:54 pm (Central Time).

By: Name: Sarah W. Hilgert